

Massachusetts Health Care Quality and Cost Council Application for Health Care Claims Data

CONTACT INFORMATION

Applicant Name	
Title	
Organization	
Address	
Telephone Number	
Fax Number	
E-mail Address	
Organization Website, if any	

- Specify the **purpose and intended use** of the data requested, including a detailed project description. [3.03(3)(b)1.] Specify research protocols, as applicable. [3.03(3)(b)10.]

DATA REQUESTED [3.03(3)(b)2.]

The Health Care Quality and Cost Council's Health Care Claims data includes three datasets: *Member Eligibility Data*, *Medical Claims Data*, and *Pharmacy Claims Data*. Data is available for claims paid beginning July 1, 2006 through 4 months prior to the application date. The complete list of data elements and their respective levels is included in Attachment A.

- Indicate the type(s), level(s), and year(s) of data you are requesting. Please note that only Massachusetts state agencies may request Level 3 data.

Dataset	Level		Year(s)
	1	2	
<i>Member Eligibility Data</i>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<i>Medical Claims Data</i>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<i>Pharmacy Claims Data</i>	<input type="checkbox"/>	<input type="checkbox"/>	_____

- Data elements requested*

Level 1 Requests

Indicate whether you are requesting all Level 1 data elements for each dataset, or if you are requesting a data abstract. If you are requesting a data abstract, mark in Attachment A each Level 1 data element you are requesting.

Level 2 Requests

Mark in Attachment A each Level 2 data element you are requesting.

- For each Level 2 data element you are requesting, justify your need for this data element to accomplish your purpose [3.03(3)(b)3.]

5. *Claims requested.* For each dataset requested, indicate whether you are requesting all claims or a data abstract. If you are requesting a data abstract, specify the data elements and the values for each data element to perform the abstraction. Refer to the data elements and values listed in regulation 129 CMR 2.00: Uniform Reporting System for Health Care Claims Data Sets.

DATA SECURITY AND INTEGRITY

6. Specify the administrative, security and privacy measures you will take to safeguard the confidentiality of patient information, patient rates, and any Level 2 data elements that the DRRB permits to be released, and to prevent unauthorized access to or use of such data. [3.03(3)(b)5.] Details should include information on access, handling and storage of the data, physical security of the data, and steps taken to safeguard patients' privacy. **Please state in detail how the original data tapes/CDs will be protected, how mainframe or pc level data files will be protected; how the data on PCs are protected from access; when/how the data will be archived or destroyed; whether confidentiality agreements are required of all employees accessing data; and other security and privacy protections.** Applicants must demonstrate that they can ensure **specifically** that patient privacy will be protected.
7. Specify your methodology for maintaining data integrity and accuracy [3.03(3)(b)6.]
8. Will you be using zip code of patient residence in your study or use?
YES ☐ NO ☐
- If YES, you and your agents are obligated to ensure that cell sizes of data as presented will not identify patients. Please explain in detail how you will do.
9. If you have requested health claims data in the past, describe or attach examples of actual studies/reports or product information for which the data were used. State whether they are representative of the purpose(s) and use(s) of this present application.
10. Detail your qualifications to perform the research described or accomplish the intended use. [3.03(3)(b)4.] Submit the résumé or curriculum vitae of the applicant/principal investigator and of all parties expected to access the data. Detail the activities each party will undertake and their qualifications to conduct those activities. [3.03(3)(b)7.] Also, if you have requested data previously, please note any changes in your researchers, investigators, or analysts from past application(s).

USE OF AGENTS OR CONTRACTORS [3.03(3)(b)8.]

11. Engagement of third party vendors

- a) Identify any agents or contractors who will perform any function with the requested health claims data, and detail their qualifications and anticipated activities.

Company Name	
Contact Person	
Title	
Address	
Telephone Number	
Fax Number	
E-mail Address	
Organization	
Website, if any	

Qualifications and activities:

Data security and integrity

Please be advised that we may contact your agent/contractor to discuss security measures.

- b) Will the agent/contractor have access to the data at a location other than your location or in an off-site server and/or database?
- c) Specify the measures your contractor/agent will use to maintain data security, patient privacy, and data integrity. Details should include information on access, handling and storage of the data, physical security of the data, and steps taken to safeguard patients' privacy. **Please state in detail how the original data tapes/CDs will be protected, how mainframe or pc level data files will be protected; how the data on PCs are protected from access; when/how the data will be archived or destroyed; whether confidentiality agreements are required of all employees accessing data; and other security and privacy protections.** The applicant must demonstrate that s/he can insure **specifically** that patient privacy will be protected.

DATA RETURN AND DESTRUCTION [3.03(3)(b)9.]

12. Recipients of Health Care Claims data are required to return the original released data to the Council and to destroy all copies of the data remaining in the recipient's, his/her employee's, and his/her agent's possession or control. Specify the measures you will use to meet these obligations.

DATA LINKAGE AND FURTHER DATA ABSTRACTION [3.03(3)(b)11.]

In cases where the data may be linked to other databases or other vital statistical information, the Board reserves the right to deny the request, grant the request but limit access to certain data elements, or perform the linkage internally and make available limited access to the linked data or a summary report.

13. Will the data be linked to aggregate level data (data not at a patient level)?

YES ☐ NO ☐

If yes, identify all linkages proposed and explain the reason(s) for each linkage.

14. Will the data be linked to other patient level data, other databases or vital statistics data?

YES ☐ NO ☐

If yes, identify all linkages proposed and explain the reason(s) for each linkage.

Specify the specific steps you will take to prevent the identification of individual patients.

15. In cases where a study proposes to identify specific medical records for further review or data abstraction, the Board may not grant access unless the proposal has received approval from the Institutional Review Board (constituted in accordance with 45 CFR 46) of the sponsoring agency, or its equivalent, and the Board is satisfied that proper safeguards for the protection of patient privacy exist.

16. Do you plan to identify specific medical records for further review or data abstraction?

YES ☐ NO ☐

If yes, please explain.

17. Do you plan to follow-up with hospitals, clinicians, other providers, payers, or health plans?

YES ☐ NO ☐

If yes, please explain.

18. Do you plan to follow-up with patients?

YES ☐ NO ☐

If yes, please explain.

RE-RELEASE OF DATA [3.03(3)(b)12.]

19. Describe your plans to publish or otherwise disclose any Health Care Claims data elements, or any data derived or extracted from such data, in any paper, report, website, statistical tabulation, or similar document.

20. Will you use the data for consulting purposes?

YES ☐ NO ☐

21. Will you be selling standard report products using the data?

YES ☐ NO ☐

22. Will you be selling a software product using the data?

YES ☐ NO ☐

If yes to any 21 or 22, please (i) describe the types of products, services or studies; (ii) estimate the number and types of clients for which the data will be used and (iii) describe any re-release of data by your clients.

APPLICATION FEE OR WAIVER REQUEST [3.03(3)(b)13.]

26. The release of Health Care Claims data requires an application fee based on all agency costs associated with maintaining and providing access to the data . In special circumstances of demonstrated need, the DRRB is authorized to waive the fee for this dataset. If you wish to apply for a waiver, please attach a letter to the Application explaining why a waiver is necessary. The fee waiver decision will be made by the DRRB and the applicant will be notified of the decision regarding such a waiver in the general notification letter. The DRRB may waive the fee in the following circumstances: (a) requests by CMS or an agency of the Commonwealth, or (b) requests by researchers or by non-profit organizations who can demonstrate that imposition of a fee would constitute a hardship. [3.05]

Will you be requesting a fee waiver?

YES ☐ NO ☐

DATA DISCLOSURE AND USE ASSURANCES [3.04]
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In consideration of any data received, it is agreed that:

- (a) The applicant, his/her employees, and his/her agents or contractors shall use the Health Care Claims Data only for the purpose stated in the request.
- (b) The applicant shall limit access to the Health Care Claims Data to authorized employees, agents, or contractors as are reasonably necessary to undertake the permitted data uses, and shall ensure that all such employees, agents, and contractors with access to the data comply with all data privacy and security protections and data use restrictions, prohibitions and protections set forth in regulation 120 CMR 3.00 and in the Data Use Agreement with the Council. To that end, the applicant shall obtain the written assurances of any authorized agent or contractor to comply with data privacy and security protections and data use restrictions, prohibitions and protections set forth in these regulations and in the Data Use Agreement, including reporting to the applicant any use or disclosure of Health Care Claims Data that is not provided for in the Data Use Agreement.
- (c) The applicant, his/her employees, and his/her agents or contractors shall not use the Health Care Claims Data, alone or in combination with any other data, to identify individual patients, clinicians or payment rates, nor will the applicant, his/her employees, and his/her agents or contractors attempt to identify individual patients, clinicians, or payment rates from the data, or to contact individual patients or clinicians.
- (d) The applicant, his/her employees, and his/her agents or contractors shall not use the Health Care Claims Data, alone or in combination with any other data, in ways that enable or permit collusion or anti-competitive conduct.
- (e) The applicant, his/her employees, and his/her agents or contractors shall not sell the Health Care Claims Data, nor use the data for any marketing or commercial purposes.
- (f) The applicant, his/her employees, and his/her agents or contractors shall retain the requested Health Care Claims Data only as long as is necessary to accomplish the applicant's intended use or purpose. The applicant, his/her employees, and his/her agents or contractors shall return to the Council or destroy, in the Data Release Review Board's discretion, all such data, including any copies of the data, as soon as he/she has accomplished that purpose or use. The Data Release Review Board may limit the amount of time within which an applicant may retain data.
- (g) The applicant, his/her employees, and his/her agents or contractors shall not reuse, manipulate, or re-aggregate Health Care Claims Data for purposes other than those approved by the Data Release Review Board.
- (h) The applicant shall immediately report to the Data Release Review Board any use or disclosure of Health Care Claims Data that is not provided for in the Data Use Agreement and shall immediately attempt to retrieve such data and take other appropriate actions to limit the known harmful consequences of the non-permitted use of disclosure.

- (i) The applicant, his/her employees, and his/her agents shall permit the Council, its employees, and its designated agents to audit the applicant's compliance with the requirements of the Data Use Agreement at any time.
- (j) An applicant shall not publish or otherwise disclose any Level 1, Level 2 or Level 3 Data Elements, or any data derived or extracted from such data, in any paper, report, website, statistical tabulation, or similar document unless such paper, report, website, statistical tabulation, or similar document conforms to the standards for de-identification set forth under 45 CFR 165.514(a), (b)(2), and (c). Nor shall any such public paper, report, website, statistical tabulation, or similar document contain individual payment rates, report any data on ten or fewer individuals or data derived from ten or fewer claims, or include any other matter that the Council has precluded for release in the Data Use Agreement.
- (k) The Massachusetts Health Care Quality and Cost Council will be cited as the source of the data in any studies, reports, or products in which the health care claims data is used.
- (l) The Massachusetts Health Care Quality and Cost Council assumes no responsibility for conclusions drawn from any analysis of data that is provided to the applicant.
- (m) The Board requires the applicant to enter into a confidentiality agreement and to indemnify the Massachusetts Health Care Quality and Cost Council against any and all claims arising from the provision and use of any data released to the applicant including, but not limited to, any breach of patient confidentiality by the applicant or its employees, agents, or contractors.

The Board requires all clients of the original data receiver to adhere to the confidentiality and security requirements contained in this application. Each client needs to sign and return to the data holder the confidentiality assurances prior to release of Level 1 data.

- (n) If the applicant prepares a report based upon Level 2 or Level 3 data, the applicant will submit either a copy of the report, or a proposal for a standard report format, to the Board at least 30 days prior to releasing the report to another person or entity so that the Board can determine whether the privacy rights of any data subject would be violated by such release.

Data Disclosure and Use Assurances Signature Page
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The undersigned hereby agrees to comply with requirements set forth herein and in **Regulation 129 CMR 3.00: Disclosure of Health Care Claims Data**. The undersigned acknowledges that

failure to adhere to these requirements could result in forfeiture of data received and forfeiture of the right to receive case mix and charge data in the future, as well as other applicable statutory sanctions.

Name of Applicant:

Title of Applicant:

Applicant's Organization:

Date _____

Signature of Applicant

FOR HCQCC USE ONLY

Receipt Confirmed By: _____ Date: _____

Health Care Quality and Cost Council Data Use Agreement

The undersigned Applicant acknowledges that:

- 1) it is the policy of the Health Care Quality and Cost Council to safeguard the privacy rights of the health care claims data subjects while permitting limited access to such data where such access serves the public interest;
- 2) the Applicant has submitted an Application **for Member Eligibility, and/or Medical Claims, and/or Pharmacy Claims data** which are confidential and subject to the re-release restrictions set forth in Regulation 129 CMR 3.04; and
- 3) the Health Care Quality and Cost Council's Data Release Review Board has determined, based upon the statements in the submitted Application, that the Applicant has fulfilled the criteria set forth in Regulation 129 CMR 3.03 for receipt of Level ____ Health Care Claims Data.

The undersigned Applicant and all its authorized representatives, subcontractors, agents and employees, in consideration of the receipt of the Level ____ **Member Eligibility, and/or Medical Claims, and/or Pharmacy Claims data**, agree that they will observe the following conditions of use regarding the detailed Health Care Claims files, or any data subsets derived from such files:

- 1) the data will not be re-released, except that it will be used or disclosed only as stated in the Application as approved; any other uses will be subject to a new Application approved by the Board;
- 2) no attempt will be made to use any data to learn the identity of specific patients, and the confidentiality of all the data, information, analyses and reports shall be strictly maintained;
- 3) at a minimum, the security and privacy measures stated in the Application will be taken in order to safeguard patient privacy and to prevent unauthorized access to, use or disclosure of such data;
- 4) the applicant will immediately report to the Board any unauthorized use or disclosure when the applicant becomes aware of it;
- 5) no data base linkages may occur except as specified below:

- 6) upon completion of the project described in the Application, the data will be destroyed or returned to the HCQCC;

Upon completion of the project described in the Application, the applicant agrees to complete and return to the Board a "Certification of Project Completion & Destruction or Retention of Data". In cases where there is a valid justification

approved by the Board for retaining the data, the applicant agrees to continue the privacy protections for as long as the information is retained. When retention of the data is no longer justified and/or required by law, the recipient agrees to return the data or to certify to the Board (via completion of the same Certification Form) that the data have been destroyed.

- 7) any employee, subcontractor or agent which processes data on behalf of the Applicant and any recipient of data will be bound by all these restrictions and conditions set forth in this Agreement and Regulation 129 CMR 3.00;
- 8) the Applicant agrees to indemnify, defend, and hold harmless the Massachusetts Health Care Quality and Cost Council, and its members, employees, representatives, and agents against all claims, losses and liability arising from the Applicant's receipt and further use or disclosure of Council data accruing to any person, organization or other legal entity.
- 9) The Applicant agrees to reimburse the Health Care Quality and Cost Council, its members, representatives, and agents for all damages and costs, including litigation costs, court costs, and attorneys' fees incurred in enforcing any provision of its enabling statute, regulations or this agreement, or incurred by the Council in pursuing sanctions for violations of its regulations, or securing the termination of use and the return of all data provided by the Council to the Applicant.
- 10) The Board requires all clients of the original applicant to adhere to the confidentiality and security requirements contained in this application. Each client needs to sign and return to the original applicant the confidentiality assurances prior to re-release of Level 1 data.**
- 11) For Level 2, no data containing data elements which are organized by Member Identification Code (MIC) will be released to any other person or entity, except that the applicant may release a summary study which aggregates multiple records organized by MIC and which does not disclose the actual MIC or any other Level 2 or 3 data element;
- 12) If the applicant prepares a report based upon Level 2 data, including summary studies which aggregate multiple records organized by MIC, the applicant will submit either a copy of the report, or a proposal for a standard report format, to the Board prior to releasing the report to another person or entity so that the Board can determine whether the privacy rights of any data subject would be violated by such release;
- 13) Applicant agrees to acknowledge the Massachusetts Health Care Quality and Cost Council as the source of the data in all reports, publications or products based on these data; however applicant will clearly state that interpretations are its own and not those of the Council and;
- 14) Applicant agrees to provide the Council an abstract and reference for any published research material resulting from the use of these data.
- 15) additional conditions specific to this Application are attached as Attachment A and incorporated herein:
___ yes ___ no;

Confidentiality Agreement for the Use of Health Care Claims Data Signature Page

I understand and agree to the above conditions required by the Massachusetts Health Care Quality and Cost Council for data release and further agree to comply with the Massachusetts Fair Information Practices Act, Chapter 66A, and Regulation 129 CMR 3.00. My signature indicates my agreement to comply with the above-stated restrictions and conditions required for data to be released by the Council for the uses approved by the Board.

If the principal investigator for a non-corporate applicant is changing, the Review Board must be advised of the change, and may require additional assurances or re-execution of relevant documents.

AUTHORIZED

SIGNATORY: _____

(Signature: Application must be signed by a duly authorized representative of applicant)

Print Name: _____

Title: _____

Date: _____

(Check One): _____ Organization _____ Individual

Full Legal Organization or Individual Name: _____

Doing Business As: Name (If Different): _____

Tax Identification Number: _____

Address: _____

Telephone: _____ FAX: _____

Email: _____

Certification of Project Completion & Destruction or Retention of Data

NOTE: Data must be destroyed so that it cannot be recovered from the electronic storage media. Acceptable methods include the use of file wiping software implementing at a minimum DoD.5200.28-STD (7) disk wiping, and the degaussing of backup tapes. Electronic storage media such as floppy disks, CDs, and DVDs used to store data must be made unusable by physical destruction.

The undersigned data recipient hereby certifies that the project described in the Application is complete as of {___SPECIFY DATE ___}. We further certify as follows (check the appropriate section):

_____ I/We certify that we have destroyed all data received from the Council in connection with the aforementioned project, in all media that was used during the research project. This includes, but is not limited to data maintained on hard drive(s), diskettes, CD's, etc.

_____ I/We certify that we are retaining the data received in connection with the aforementioned project, pursuant to the following health or research justification. Describe in detail and indicate the timeframe, if any.

_____ I/We hereby certify that we are retaining the data received from the Council in connection with the aforementioned project, as required by the following law. Reference the appropriate law and indicate the timeframe.

Year(s) of data requested: _____

Version of data: _____

Destroyed: ☐ Yes ☐ No

Dated: _____

Signature of Applicant

Organization

Dated: _____

By: _____
Signature on behalf of Applicant's Organization

APPLICATION SUMMARY SHEET/CHECKLIST

Please complete and **return by email** this checklist along with the application.
Thank you.

Data Type Requested

Member Eligibility ☐

Medical Claims ☐

Pharmacy Claims ☐

Year(s) requested: _____

Highest Level Applying for: _____

Security Measures Included?: YES ☐ NO ☐

Curriculum Vitae/résumé of principal researchers **AND** applicant included?
YES ☐ NO ☐

Intended Use(s) of Data

Check *all* lines that describe your **intended use(s)** of the data requested.

Clinical research ☐

Health services research ☐

Analyses to address
public policy issues ☐

Analyses to address private
policy issues ☐

Create products and tools (e.g., quality measurements, severity adjustment software) ☐

Health outcomes ☐

Quality ☐

Medical practice patterns ☐

Cost ☐

Utilization ☐

Access ☐

Markets ☐

Other (please describe below) ☐

=====

The following section is for Board use only:

Date Received: _____

Data Use Classification:

Single use:

Limited multiple uses:

Multiple uses:
